Claims

1. A method for compensating for subject-specific variability in an apparatus intended for non-invasively determining the amount of at least two light-absorbing substances in the blood of a subject and provided with emitter means for emitting radiation at a minimum of two different wavelengths and with detector means for receiving the radiation emitted, the method comprising the steps of

- calibrating the apparatus using a nominal calibration,
- carrying out initial characterization measurements, said measurements to include measuring radiation received by the detector;
- based on the characterization measurements, establishing nominal characteristics describing conditions under which the nominal calibration is used;
- storing reference data indicating the nominal characteristics established,
- performing in-vivo measurements on a living tissue, wherein radiation emitted through the tissue and received by the detector means is measured,
- based on the in-vivo measurements and the reference data stored, determining tissue-induced changes in the nominal characteristics; and
- compensating for subject-specific variation in the in-vivo measurements by correcting the nominal calibration on the basis of the tissue-induced changes.

2. A method according to claim **1**, including compensation for effects causing wavelength shift.

3. A method according to claim **1**, including compensation for effects internal to the tissue.

4. A method according to claim **1**, including both compensation for effects causing wavelength shift and for effects internal to the tissue.

5. A method according to claim **2**, wherein the compensation for effects causing wavelength shift includes defining subject-specific extinction coefficients for the substances.

6. A method according to claim **3**, wherein the compensation for effects internal to the tissue includes defining a subject-specific transformation used to transform in-vivo measurement results to the Lambert-Beer model.

7. A method according to claim **4**, wherein the compensation for effects causing wavelength shift includes defining subject-specific extinction coefficients for the substances, and the compensation for effects internal to the

tissue includes defining a subject-specific transformation used to transform in-vivo measurement results to the Lambert-Beer model.

8. A method according to claim **5**, wherein said establishing step includes determining DC transmission characteristics of the emitter and detector means, spectral characteristics of the emitter and detector means and nominal transmission characteristics for the tissue.

9. A method according to claim **8**, wherein said establishing step further includes determining the temperature in which the nominal calibration is used.

10. A method according to claim **9**, wherein the extinction coefficients $\varepsilon_{i,j}$ are determined according to the following formula:

$$\varepsilon_{ij}^{effective} = \frac{1}{W}\int_{\Delta\lambda}\varepsilon_j(\lambda) * LED_i(\lambda(T)) * DET(\lambda) * tissue(\lambda)\partial\lambda\ ,$$

where the integration is over the emission spectrum $LED_i(\lambda)$ of the emitter means, $DET(\lambda)$ represents the spectral sensitivity of the detector means, $tissue(\lambda)$ is the spectral transmission of radiation through the tissue, ε is the extinction coefficient of the substance, T is the temperature, and i and j are matrix indices.

11. A method according to claim **10**, wherein

- the step of establishing nominal characteristics includes defining a nominal extinction matrix with a nominal extinction coefficient for each substance/wavelength pair, and

- the step of determining tissue-induced changes includes updating the nominal extinction matrix, whereby the updated matrix includes the subject-specific extinction coefficients to be used in the Lambert-Beer model.

12. A method according to claim **11**, wherein the nominal extinction matrix is determined according to the following formula

$$\varepsilon_{ij}^{effective} = \frac{1}{W}\int_{\Delta\lambda}\varepsilon_j(\lambda) * LED_i(\lambda(T)) * DET(\lambda)\partial\lambda$$

where the integration is over the emission spectrum $LED_i(\lambda)$ of the emitter means, $DET(\lambda)$ represents the spectral sensitivity of the detector means; ε is the extinction coefficient of the substance, T is the temperature, and i and j are matrix indices.

13. A method according to claim **11**, wherein the step of establishing nominal characteristics further includes determining a first shift matrix, the elements of which indicate a relative change in each extinction coefficient,

assuming that the slope of the term *tissue*(λ) has a fixed value deviating from zero.

14. A method according to claim **13**, wherein the step of determining tissue-induced changes in the nominal characteristics includes defining (1) the slope of the term *tissue*(λ) and (2) the subject-specific extinction coefficients based on the shift matrix and the slope defined.

15. A method according to claim **6**, wherein the method further includes the steps of

- storing an average transformation measured for a great number of subjects and
- based on the tissue-induced changes, updating the average transformation, whereby the updated transformation represents the subject-specific transformation.

16. A method according to claim **10**, wherein

- the step of establishing nominal characteristics further includes defining temperature dependence of the emitter and detector means; and
- said compensating step includes temperature compensation for the emitter and detector means.

17. A method according to claim **16**, wherein the step of establishing nominal characteristics further includes determining a second shift matrix the elements of which indicate a relative change of each extinction coefficient for a predetermined wavelength shift.

18. A method according to claim **17**, wherein the step of determining tissue-induced changes in the nominal characteristics includes

- defining a wavelength shift caused by temperature and
- defining subject-specific coefficients based on the shift matrix and the wavelength shift defined.

19. A method according to claim **7**, wherein

- the step of defining nominal characteristics includes calculating nominal values for the Functional Light Transmission (FLT) of the apparatus,
- the step of determining tissue-induced changes includes calculating new values for the Functional Light Transmission (FLT) of the apparatus, and

the step of compensating includes determining the subject-specific transformation on the basis of the nominal and new values.

20. A method according to claim **7**, wherein

- the step of defining nominal characteristics includes calculating nominal values for function F_{kl} of the apparatus,

- the step of determining tissue-induced changes includes calculating new values for the function F_{kl} of the apparatus, and

- the step of compensating includes determining the subject-specific transformation on the basis of the nominal and new values,

wherein the function F_{kl} corresponds to the ratio $\frac{f_a(\mu_a^k - \mu_v^k) + \mu_v^k}{f_a(\mu_a^l - \mu_v^l) + \mu_v^l}$, where μ_V and μ_a are the absorption coefficients of venous and arterial blood, respectively, as determined in the Lambert-Beer domain, f_a is the volume fraction of arterial blood, and the superscripts *k* and *l* indicate the wavelength.

21. A method according to claim **20**, wherein the nominal and new values for the Function F_{kl} are calculated on the basis of measured fluctuation of the DC component of the radiation received by the detector means.

22. A method according to claim 20, wherein

- the step of determining tissue-induced changes includes calculating a first approximation for the amount of the substances, and

- the step of compensating includes utilizing the first approximation for determining the subject-specific transformation.

23. A method according to claim **1**, wherein the at least two light absorbing substances include oxyhemoglobin (HbO2) and reduced hemoglobin (RHb).

24. An apparatus for non-invasively determining the amount of at least two light absorbing substances in the blood of a subject, the apparatus comprising

- emitter means for emitting radiation at a minimum of two different wavelengths,

- detector means for receiving said radiation at each of said wavelengths and producing at least two electrical output signals,

- first signal processing means for processing said output signals and producing a modulation signal for each wavelength, each modulation signal representing the pulsating absorption caused by the arterialized blood of the subject,

- second signal processing means for applying a predetermined calibration on said modulation signals, whereby transformed modulation signals applicable in the Lambert-Beer model are obtained,

- memory means for storing reference data indicating nominal characteristics under which said predetermined calibration has been applied,

- first compensation means, operatively connected to the memory means, for determining tissue-induced changes in the nominal characteristics,

- second compensation means, operatively connected to the first compensation means, for defining a subject-specific calibration by correcting the predetermined calibration on the basis of the tissue-induced changes, and

- calculation means, responsive to the second compensation means, for determining said amounts.

25. A sensor for collecting measurement data for a pulse oximeter intended for non-invasively determining the amount of at least two light absorbing substances in the blood of a subject, the sensor comprising:

- means for emitting radiation at a minimum of two different wavelengths,

- means for receiving said radiation at each of said wavelengths and producing at least two electrical output signals;

- storage means including reference data indicating nominal characteristics describing calibration conditions of the pulse oximeter, said data allowing an apparatus connected to the sensor to determine tissue-induced changes in the nominal characteristics when radiation is emitted through said tissue.

26. A sensor according to claim **25**, wherein the means for emitting radiation are Light Emitting Diodes.

27. A sensor according to claim **25**, wherein the means for emitting radiation are lasers.

28. A sensor according to claim **25**, wherein the means for emitting radiation include radiation conduction means for conducting radiation from the emitting component to the tissue site, at which the measurement is performed.

29. A sensor according to claim **25**, wherein the means for receiving radiation include radiation conduction means for conducting radiation from the tissue site to the detector component.

30. A sensor according to claim **25**, wherein the reference data includes the Functional Light Transmission (FLT) of the apparatus.

31. A sensor according to claim **25**, wherein the reference data includes function F_{kl} of the apparatus in nominal conditions,

wherein the function F_{kl} corresponds to the ratio $\frac{f_a(\mu_a^k - \mu_v^k) + \mu_v^k}{f_a(\mu_a^l - \mu_v^l) + \mu_v^l}$,

where μ_V and μ_a are the absorption coefficients of venous and arterial blood,

respectively, as determined in the Lambert-Beer domain, f_a is the volume fraction of arterial blood, and the superscripts k and l indicate the wavelength.